



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Robert K. Evans

Serial No.

09/888,304

Filed:

June 22, 2001

Eor:

POLYNUCLEOTIDE VACCINE ADJUVANTS AND

FORMULATIONS CONTAINING CATIONIC SURFACTANTS AND METHODS OF USE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Art Unit: <u>1633</u>

Examiner:

Wehbe, Anne Marie

Sabrina

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- 4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By C.Rapucki Date 5-8-07

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION					
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE			
··· ··· ··· ··· ··· ·· ·					
If this is inconvenient, additional copies will be submitted	upon request.				
6. In accordance with 37 C.F.R. 1.97, (check one)					
the attached information is filed within three months of	of the filing date of the captioned case.				
the attached information is filed more than three mon Office Action on the merits.	ths after the filing date but prior to the	mailing of a first			
the attached information is filed before the mailing of examination under §1.114.	a first Office action after the filing of a	request for continued			
the attached information is being filed more than thre Office Action on the merits, but before the mailing da otherwise closes prosecution in the application. The Account No. 13-2755 for the fee required under 37 C	te of a Final Action, Notice of Allowanc enclosed authorization is therefore give	e, or an action that			

each item of information contained in this Information Disclosure Statement was first cited in any communication

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designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.

from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this

from a foreign patent office in a counterpart application and this communication was not received by any individual

no item of information contained in this Information Disclosure S foreign patent office in a counterpart foreign application, and, to after making reasonable inquiry, was known to any individual demonths prior to the filing of this Statement.	the knowledge of the person signing the certification
	Respectfully submitted,
	Al p.n
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Date: May 8, 2007

Statement.

ı	Substitute for form 1449A/PTO		COMPLETE IF KNOWN			
	INFORMATION DISCLOSURE			CLOSURE	Application Number	09/888,304
ATPE				DY ICANIT	Filing Date	June 22, 2001
STATEMENT BY APPLICANT		First Named Inventor	Robert K. Evans			
MAT. 1 0. 2007				,	Group Art Unit	1633
(the as many sheets as necessary)	Examiner Name	Wehbe, Anne Marie Sabrina				
V.	ADEMAR	1	of	2	Attorney Docket Number	20703Y

·			U.S. PA	ATENT DOCUMENTS	
Examiner Initials*	Cite No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	A01	2,674,619		Lunsted	04/06/1954
	A02	4,344,934		Martin et al.	08/17/1982
	A03	5,567,859		Kabanov et al.	08/12/1997
	A04	5,656,611		Emanuele et al.	12/09/1997
	A05	5,691,387		Emanuele et al.	10/22/1996
	A06	5,696,298		Emanuele et al.	11/25/1997
	A07	5,990,241		Emanuele et al.	11/23/1999
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	A09	6,086,899		Balasubramanian et al.	07/11/2000

Č.			FOREIG	N PATENI	DOCUMENTS	
Examiner	Cite No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication of
Initials*		Office	Number	Kind Code (if known)	of Cited Document	Cited Document MM-DD-YYYY
	B01	PCT	WO 96/04932		Cytrx Corporation	02/22/1996
	B02	РСТ	WO 97/40839		Merck & Co., Inc.	11/06/1997
	B03	PCT	WO 97/42962		Bergeron et al.	11/20/1997
	B04	PCT	WO 98/35562		Merck & Co., Inc.	08/20/1998
	B05	PCT	WO 99/06055	A Dr. A	Supratek Pharma Inc.	02/11/1999
	B06	PCT	WO 99/21591		American Home Products Corp.	05/06/1999

Examiner Signature Date Considered

Substitute for form 1440B/DTO		COMPLETE IF KNOWN			
Substitute for form 1449B/PTO INFORMATION DISCLOSURE		Application Number	09/888,304		
S	TATEMENT DV	AD	DI ICANT	Filing Date	June 22, 2001
STATEMENT BY APPLICANT		First Named Inventor	Robert K. Evans		
	(Group Art Unit	1633
(use as many sheets as necessary)		Examiner Name	Wehbe, Anne Marie Sabrina		
Sheet	2	of	2	Attorney Docket Number	20703Y

		NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	C01	Newman et al., "Development of adjuvant-active nonionic block copolymers", Advanced Drug Delivery Reviews, Vol. 32, No. 3, pp. 199-223 (1998)
	C02	Newman et al., "Use of Nonionic Block Copolymers in Vaccines and Therapeutics", Critical Reviews in Therapeutic Drug Carrier Systems, Vol. 15(2), pp. 89-142 (1998)
	C03	Todd et al., "Development of an adjuvant-active nonionic block copolymer for use in oil-free subunit vaccines formulations", Vaccine, Vol. 15, No. 5, pp. 564-570 (1997)
	C04	Todd et al., "Aqueous formulation of adjuvant-active nonionic block copolymers", Methods Mol Med, Vol. 42: Vaccine Adjuvants: Preparation Methods and Research Protocols, Humana Press, p. 121-136 (2000)
	C05	Handbook of Pharmaceutical Excipients, 2nd Ed., Edited by A. Wade and P.J. Weller, American Pharmaceutical Association, Washington; The Pharmaceutical Press, London, pp. 27-29, 30-31, 96-98, 636 (1994)
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Examiner Signature	Date Considered	